

### **REMARKS**

Claims 1-35 are pending. Applicants wish to thank Examiners Achutamurthy and Ponnaluri for the courteous and helpful interview held on March 31, 1999. In accordance with that discussion, claim 1 has been amended to more clearly define the invention. Applicants respectfully request reconsideration and allowance of the claims now pending.

### **THE INVENTION**

The invention relates to compositions of multivesicular liposomes useful as a drug delivery system and processes for their manufacture.

#### **I. Rejection Under 35 U.S.C. §112, First Paragraph**

Claims 1-34 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner states:

The claims are drawn to multivesicular liposomes (MLV) prepared by the recited method which comprises, among other steps, one step wherein a "first aqueous component" is added in making a water-in-oil emulsion and another step wherein a "second aqueous" component is added. However, nowhere in the specification [is there sic] to be found a clear description what constitutes the "first aqueous component" and the "second aqueous component".

(Office Action at page 3). Applicants respectfully traverse this rejection.

Additionally, Claims 1-34 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to practice the claimed invention.

The Examiner states in part:

“... one having ordinary skill in the art would not be able to practice the invention because they would not know what to use as the aqueous component that would yield the multivesicular liposomes with the defined morphological characteristics.”

(Office Action at page 4). Applicants respectfully traverse this rejection.

In addition to the comments provided in the Response filed on March 29, 1999, and in accordance with the request of the Examiner, submitted herewith is a Declaration under 37 CFR 1.132 which addresses the rejections made under 35 U.S.C. §112, first paragraph by demonstrating that the term “aqueous” is a common term with a standard definition, and is well recognized in the conventional art of making liposomes. Furthermore, the Declaration addresses the Examiner’s comments with respect to the “first” and “second” aqueous components.

## **II. Rejection Under 35 U.S.C. §112, Second Paragraph**

Claims 1-34 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention.

The Examiner states in the rejection:

“The expression “nonhydrohalic acid” is vague and indefinite in the absence of specifying the intended acid.”

(Office Action at page 4). Applicants respectfully traverse this rejection.

This rejection has been fully addressed in the Response filed on March 29, 1999.

In summary, for the reasons set forth herein, Applicants maintain that claims 1-35 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action and allow the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants’ representative can be reached at (619) 678-5070.

Please charge any additional fees, or make any credits, to Deposit Account No.  
06-1050.

Respectfully submitted,

Date: 4.29.99



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